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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/461,774      | 12/15/1999  | LILY CHAN            | 1781-180P           | 4250             |

7590 04/07/2004

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EXAMINER

SWARTZ, RODNEY P

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1645

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/461,774

**Applicant(s)**

CHAN ET AL.

**Examiner**

Rodney P. Swartz, Ph.D.

**Art Unit**

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22December2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 27-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

1. Applicants' Response to Office Action, received 22December2003, is acknowledged.

Claims 1-26 have been canceled. New claims 27-47 have been added.

2. Claims 27-47 are pending.

### **Rejections Moot/Withdrawn**

3. The rejection of claims 1-7 under 35 U.S.C. 112, second paragraph, indefiniteness, for "substantially", is moot in light of the cancelation of the claims.
4. The rejection of claims 1-7 under 35 U.S.C. 102(b) as being anticipated by Thybo et al (*Tubercle and Lung Disease*, 76:149-155, 1995) is moot in light of the cancelation of the claims.
5. The rejection of claim 9 under 35 U.S.C. 112, first paragraph, scope of enablement, is moot in light of the cancelation of the claim.

### **New Rejections Necessitated by Amendment**

#### **Claim Rejections - 35 USC § 112**

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 27-47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific polypeptides consisting of specific sequences taught in the specification, does not reasonably provide enablement for any isolated polypeptide which "comprises" or "has" sequence id no. 4, 6, 8, 10, or  $\geq 70\%$  identity to 4, 6, 8, or 10. The

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specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant claims are drawn to an isolated polypeptide which "comprises" or "has" SEQ ID NO:4, 6, 8, or 10 or a sequence which is  $\geq 70\%$  identical to 4, 6, 8, or 10, wherein said polypeptide exhibits claimed reactivity with sera from infected or noninfected individuals.

The instant specification teaches reactivity with sera from infected or noninfected individuals using specific proteins (Ex. 7-9). The instant specification does not provide sufficient guidance or examples for the instant claims. The claims encompass not only sequences utilized in the examples, but the open language of the claims, i.e., "comprising" or "has", encompasses polypeptides which may have an undetermined number of amino acids outside of the identified sequence. Thus, if a sera from an individual reacts with this unknown region(s), how does one of skill in the art determine if this is due to antibody against *Mycobacteria*?

9. Claims 27-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to an isolated polypeptide which exhibits reactivity of 5% to 90% with antisera obtained from subjects that have been infected by a *Mycobacterium* species and wherein said polypeptide exhibits a reactivity of 0% to 25% with sera obtained from subjects that have not been previously infected by a *Mycobacterium* species.

The percent reactivity is indefinite because it is totally dependant upon the number of subjects being tested. For instance, if one is testing one infected and one noninfected

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individual, how does one determine whether the claimed polypeptide fits the reactivity level required in the claims.

### Conclusion

10. No claims are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER  
Art Unit 1645

April 5, 2004